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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,184	01/24/2001	Britton Chance	08326-045002	8248
7590		07/06/2004	EXAMINER	
John N William		SMITH, RUTH S		
Fish & Richardson		ART UNIT		
225 Franklin Street		PAPER NUMBER		
Boston, MA 02110-2804		3737		

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/622,184

Applicant(s)

CHANCE, BRITTON

Examiner

Ruth S Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 36 (second occurrence) has been renumbered claim 38.

Claims 18,35 are objected to because of the following informalities: In claim 18, it is unclear as to which detector is being referred to on line 4. In claim 35, line 11, "at" should be inserted before "least". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,6-18,29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370). Chance et al disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient in that the use of such information for this purpose is a well known expedient in the art. It would have been obvious to one skilled in the art that the system of Chance et al could be used to examine any type of tissue in a body such as breast tissue. The system is capable of examining such tissue type. With respect to claim 6, it can be seen from figures 7-7A that a plurality of optical modules can be used

to acquire data from a plurality of locations on the patient. With respect to claims 7-9, the manner in which the data from the two data sets are compared would have been an obvious design choice of known functional equivalents in the art.

Claims 3-18,29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370) in view of Hochman et al (5,845,639). Chance et al disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient. It would have been obvious to one skilled in the art that the system of Chance et al could be used to examine any type of tissue in a body such as breast tissue. The system is capable of examining such tissue type. With respect to claim 6, it can be seen from figures 7-7A that a plurality of optical modules can be used to acquire data from a plurality of locations on the patient. With respect to claims 7-9, the manner in which the data from the two data sets are compared would have been an obvious design choice of known functional equivalents in the art. Chance et al fail to disclose the use of a reference to compared the data against to aid in making a diagnosis. Hochman et al is just one example of many which disclose an optical system for analyzing tissue by comparing data obtained from the examine tissue with data obtained from a reference sample having a known condition. It would have been obvious to one skilled in the art to have modified Chance et al such that the data is compared to a reference sample in that is such a well known expedient in the art to ensure an accurate diagnosis.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370) in view of Chance (5,564,417)). Chance et al ('370) disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are

provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient. It would have been obvious to one skilled in the art that the system of Chance et al could be used to examine any type of tissue in a body such as breast tissue. The system is capable of examining such tissue type. Chance et al fail to disclose the specific structure of the spectrophotometer to process the emitted and detected light. Chance ('417) discloses a system for imaging tissue optically using the specific optical structure as set forth in claims 19-24. It would have been obvious to one skilled in the art to have further modified Chance et al such that it includes the optical system structure as set forth in Chance. Such a modification merely involves the substitution of one well known spectrophotometer arrangement for another.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chance et al (5,853,370) in view of Chance (5,807,263)). Chance et al ('370) disclose a method and apparatus for examining tissue optically using an optical module having input and output ports, a controller and a processor. A plurality of data sets are provided that include data representing both blood volume and blood oxygenation (column 8, lines 23-48). The data sets are subtracted to obtain a difference data set. It would have been obvious to one skilled in the art to have used the images to determine an abnormality present in the patient. It would have been obvious to one skilled in the art that the system of Chance et al could be used to examine any type of tissue in a body such as breast tissue. The system is capable of examining such tissue type. Chance et al fail to disclose the specific structure to process the emitted and detected light. Chance ('263) discloses a system for imaging tissue optically using the specific optical structure as set forth in claims 25-28. It would have been obvious to one skilled in the art to have further modified Chance et al such that it includes the optical system structure as set forth in Chance. Such a modification merely involves the substitution of one well known spectrophotometer arrangement for another.

### ***Response to Arguments***

Applicant's arguments filed April 12, 2004 have been fully considered but they are not persuasive. Applicant's arguments regarding Hochman are noted, however, the Hochman reference was merely used as a teaching of just one example of many which disclose an optical system for analyzing tissue by comparing data obtained from the examine tissue with data obtained from a reference sample having a known condition. Therefore, applicant's arguments regarding differing technology is not convincing. Regarding the use of the Chance et al ('370) reference as not being directed to examining breast tissue, it would have been obvious to one skilled in the art that the system of Chance et al could be used to examine any type of tissue in a body such as breast tissue. The system is clearly capable of examining such tissue type.

### ***Conclusion***

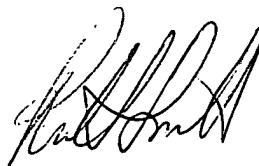
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', is positioned above the printed name.

Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS